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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,600	03/24/2004	David Nordman	L.8XC1	7238

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/809,600	NORDMAN ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,30 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,30 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The finality of the previous Office action has been withdrawn and prosecution of this application is hereby reopened. Applicant's amendment after final filed on 08 July 2010 is acknowledged and has been entered. Claims 1-26, 28, 29, 31 and 32 have been cancelled. Claims 27, 30, and 33-35 remain in the case.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 27, 30, and 33-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Hildebrand et al. (US Application 10/337,161, filed 02 January 2003, published as US 2003/0191286 A1 and in corrected form as US 2006/0276629 A9; incorporating the disclosure of US 60/413,842 therein), Douillard et al. (Meth. Enz. 92: 168, 1983), and Geysen et al. (Proc. Natl. Acad. Sci. USA 81: 3998, 1984).

Hildebrand et al. teach (see e.g., US 2003/0191286, page 15 and Figs. 79-86) a SERA SCREEN ELISA method or Luminex™ bead method for the determination of antigen-specific antibodies in human serum samples against a panel of immobilized isolated soluble HLA

molecules. In light of the disclosure of US 60/413,842 incorporated into the disclosure of the invention (see e.g. pages 1-24, 73, 74, 96-103, and 167-171 of the document detailing the ELISA protocol and various results obtained therewith), samples are tested for anti-HLA antibodies against a panel of immobilized isolated soluble HLA molecules and blanks containing blocking reagent (3% BSA), and positive responses are determined by detection of reactivities after, for example, background subtraction. Although the reference does not teach the specific method for determining positive versus negative responses, the reference does not specifically mention the use of a separate negative control serum sample as involved in the determination.

As set forth in a prior Office action, Douillard et al. teach determination of positive responses for antibody analytes with enzyme-linked immunosorbent assays. Negative controls can include irrelevant antigens (see e.g. pages 169 and 172), a set of unrelated antibodies (see e.g. pages 171-172 and 174), medium alone (see e.g. page 174), and/or buffer alone (see e.g. pages 172 and 174). Positives are those wells with values above value(s) in the well(s) chosen as the negative (see e.g. pages 172 and 174). The reference obtains an arithmetic mean of the values from all the negative controls (see e.g. pages 172 and 174) for determinations.

As set forth in a prior Office action, Geysen et al. teach determination of positive responses for antibody analytes in serum samples with enzyme-linked immunosorbent assays. Negative controls include antigens of similar structure (see e.g. Figs. 2 or 3), or antigens from a homologue from a different species (see e.g. Table 1), and/or a set of unrelated antibodies (see e.g. Fig. 2). Positives are those wells with values above value(s) in the well(s) chosen as the negative (see e.g. Figs. 2 or 3, and pages 4000-4001), which, if not a case in which all or none of the antigens react, can be the value(s) for the antigen(s) having the generally uniform

background level. The reference also clearly exemplifies an assay in which only a single capture antigen does not react and would be selected as the negative control (see e.g. Fig. 3 and Table 1, W substitution for D at position 2 (residue 147) of the peptide reacted with serum 48) based on the disclosure. The reference implicitly uses subtraction or division in determining that levels were elevated above the background.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used the conventional methods of determining negative controls and thereby positive responses taught in Douillard et al. and/or Geysen et al. in the determination of anti-HLA antibody positive responses against a panel of immobilized isolated soluble HLA molecules in Hildebrand et al. because such determinations are notoriously old and well known in the art as taught by Douillard et al. and/or Geysen et al. and one would have expected these notoriously old and well known methods to function, particularly in view of the use of related antigens and blanks in the panels of Hildebrand et al. and the lack of any specific mention of comparisons other than among these reagents with the sample under test in Hildebrand et al. It would have been further obvious to have incorporated antigens from a homologue from a different species in the methods of Hildebrand et al., as modified, because this is also a well known and conventional control useful as a negative control as taught in Geysen et al.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection set forth herein above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hildebrand et al. (US 2004/0126829 A1) also incorporate the disclosure of US 60/413,842) and teach screening sera samples with panels of soluble HLA molecules (see e.g. Fig. 28).

Hoffman et al. (US 5,599,543) teach determination of positive responses for antibody analytes in serum samples with enzyme-linked immunosorbent assays. Negative controls include irrelevant antigen control wells and/or antigen-free wells, and at least one negative control serum. The values from the negative control wells as well those of the negative control sera are subtracted from the relevant antigen wells for determinations of positive responses.

Mehta et al. (US 5,753,430) teach the routine nature of comparing sample reactivities of antibody analytes to multiple non-specific antigens (see e.g. cols. 8-11 or 15-19 or 24-26).

Tidey et al. (US 6,046,013) teach determination of anti-HLA responses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
August 16, 2010

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641